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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,911	09/05/2003	Arturo J. Angel	524522000500	7674
25226 7590 12/20/2006 MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/20/2006	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/655,911

Applicant(s)

ANGEL ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-44 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 14-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4 and 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of response dated 9-12-06 is acknowledged.

Claims 1 and 3-44 are pending. Claims 5-9 and 14-44 have been withdrawn from consideration. Claims 1, 3-4 and 10-13 have been considered for examination.

The following rejection of record has been maintained:

#### ***Claim Rejections - 35 USC § 103***

Claims 1, 3, 4 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,910,512 to Conant (Conant).

Instant claims are directed to a kit comprising as separate components, a first composition comprising capsaicin or its analog and a second component comprising a substance in which capsaicin has a solubility of at least 10%.

Conant teaches a topical analgesic composition comprising capsicum and/or capsaicin, for the treatment of pain and relief from arthritis (col. 1-2). Conant suggests a water-soluble capsaicin at a concentration of 0.1 to 1% (col. 2). Conant teaches water as an excellent for capsaicin and hence meets the claimed solubility suspending (at least 10% w/w). Conant teaches applying water-soluble capsaicin to the skin so that the epidermal layer is softened without harsh chemicals (col. 1, lines 57-60) and also teaches suspending the water-soluble capsaicin in hydrophilic bases before applying to the skin of patients to treat pain. Conant fails to teach the claimed kit having separate components. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to pack capsaicin and the solvent or the carrier for capsaicin separately and mix them before applying to skin because Conant

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teaches suspending water soluble capsaicin in various hydrophilic bases before applying to the skin for treating pain and therefore a skilled artisan would have expected capsaicin to be soluble in water and is therefore effective in treating pain, before applying.

### ***Response to Arguments***

Applicant's arguments filed 9-12-06 have been fully considered but they are not persuasive.

Applicants argue that instant claims do not recite capsaicin and the solvent or carrier mixed prior to application to skin, which is taught by Conan of record. Applicants emphasize that claims 1, 3-4 and 10-13 require the second composition is a separate component for the kit cleansing a bodily surface (described in paragraphs 11, 12, 21, 44 and 51). However, instant claims do not require the components to be separated physically or separately packaged, including those sections of instant specification cited above. A careful review of the instant specification reveals that in one embodiment the two compositions are separately packaged, whereas in another embodiment the two components are present together and the instant claims as presented read on the latter. It is argued that Conant does not mention the second component for cleansing and instead the patients (example 4 of Conan) only note that the composition worked quickly. However, instant claims are directed to a kit and the component b recites, "for cleansing" as an intended use that does not carry patentable weight.

With respect to applicants' arguments regarding the rejection of claims 1, 3-4 and 10-13 as being unpatentable over Conant in view of US 6,403,589 to Meert et al

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(Meert), the rejection has been and accordingly the arguments have not been addressed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
December 13, 2006



**LAKSHMI S. CHANNAVAJJALA**  
**PRIMARY EXAMINER**